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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/659,930	09/11/2003	Wayne E. Cornish	ACS 65357 (1512XCC)	5064

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FULWIDER PATTON LEE & UTECHT, LLP
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6060 Center Drive
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EXAMINER

APANIUS, MICHAEL

ART UNIT	PAPER NUMBER
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3736

MAIL DATE	DELIVERY MODE
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07/13/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/659,930

Applicant(s)

CORNISH ET AL.

Examiner

Michael Apanius

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 April 2007.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 64-84 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 64-84 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11 September 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 1/12/2007 has been entered. The amendments to claims 64-66 and 69 are acknowledged.

Drawings

2. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the description: all reference numerals in figure 17. Figure 17 does not appear to be mentioned in the specification. Corrected drawing sheets in compliance with 37 CFR 1.121(d), or amendment to the specification to add the reference character(s) in the description in compliance with 37 CFR 1.121(b) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet"

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or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

3. The disclosure is objected to because of the following informalities:
- a. In the amended cross-reference to related application, the information of USSN 09/881,290 should be updated.
 - b. At page 3, line 3, it appears that "is it is necessary" should be --if it is necessary--.

Appropriate correction is required.

Claim Objections

4. Claim 67 is objected to because of the following informalities: it appears that claim 67 should depend upon claim 66 instead of claim 64 as recited. Appropriate correction is required.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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6. Claim 64 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. Claim 64 is a single means claim that recites a single means limitation, "An intracorporeal device comprising an elongated member having means for causing a substantially linear change in bending stiffness over a longitudinal length of the elongated member." The claim covers every conceivable structure for achieving a substantially linear change in bending stiffness over a longitudinal length of an elongated member, while the specification discloses only those known to the inventor (MPEP § 2164.08(a)). Therefore, claim 64 encompasses undue breadth.

7. Claim 69 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The original disclosure does not appear to provide proper support for a material with changing hardness in a longitudinal direction that is configured such that the change in hardness produces a substantially linear change in bending stiffness along the length of the core member.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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9. Claims 64-68, 70-74, 76-81, 83 and 84 are rejected under 35 U.S.C. 102(b) as being anticipated by Amplatz et al. (US 4,991,602).

10. Amplatz discloses a guidewire comprising an elongated member having means (the tapered segments around 12, 22 and 24 in figure 2) for causing a substantially linear change in bending stiffness over a relatively short longitudinal length of the elongated member. It is well known in the art that non-linear curves will appear substantially linear when only considered over a relatively short length. Therefore, the tapered segments of the Amplatz guidewire are considered to cause a substantially linear change in bending stiffness when considered over only a relatively short longitudinal length of the elongated member.

11. In regards to claim 65, the taper angle continuously changes near 22 in figure 2 producing a curvilinear profile. In regards to claims 66 and 67, the elongated member has a plurality of tapered segments (12), each having a constant taper angle. In regards to claim 68, the elongate core member has at least three tapered segments as noted above. In regards to claim 70, the elongated member tapers distally (around 12 in figure 1) to a more flexible distal portion.

12. At a length L equal to zero from a starting diameter D_0 , the diameter of the guidewire corresponds to the equation set forth in claim 71. At a length L equal to zero from a starting diameter D_0 , the moment of inertia of the guidewire corresponds to the moment of inertia set forth by the equation in claim 78. The claimed equations significantly simplify when $L=0$. When solved for only $L=0$, the prior art guidewire reads on claims 71 and 78.

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13. In regards to claims 72 and 79, the core member is formed of Nitinol (column 2, lines 30-32). In regards to claims 73, 74, 80 and 81, the core member may be coated with a lubricious coating (column 5, lines 15-25). In regards to claims 76, 77, 83 and 84, the guidewire comprises at least 6 tapered segments (12, 22, 24 on each end of the guidewire).

14. Claims 64, 66-72, 75-79 and 82-84 are rejected under 35 U.S.C. 102(b) as being anticipated by Urick (US 5,497,786).

15. Urick discloses a guidewire comprising an elongated member having a plurality of tapered segments (12, 14, 16, 18). It is well known in the art that non-linear curves will appear substantially linear when only considered over a relatively short length. Therefore, the tapered segments of the Urick guidewire are considered to cause a substantially linear change in bending stiffness when considered over only a relatively short longitudinal length of the elongated member.

16. In regards to claim 66-68 and 70, the tapered segments each have a substantially constant taper angle and taper to a more flexible distal portion. In regards to claim 69, Urick discloses a material with changing hardness (30 in figure 3).

17. At a length L equal to zero from a starting diameter D_0 , the diameter of the guidewire corresponds to the equation set forth in claim 71. At a length L equal to zero from a starting diameter D_0 , the moment of inertia of the guidewire corresponds to the moment of inertia set forth by the equation in claim 78.

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18. In regards to claims 72 and 79, the core member is formed of stainless steel (column 2, lines 44-49). In regards to claims 75 and 82, a flexible body (26) is disposed about and secured to a distal core section. In regards to claims 76, 77, 83 and 84, the guidewire comprises at least 5 tapered segments (12, 14, 16 and 18 as shown in figure 1 and on each side of 19 as shown in figure 3).

Double Patenting

19. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

20. A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory

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double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

21. Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

22. Claims 64-68 and 70 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over at least claims 1-7 of U.S. Patent No. 6,666,829. Although the conflicting claims are not identical, they are not patentably distinct from each other because the patented claims recite all of the features of the broader claims of the instant application. Therefore, the instant claims are "anticipated" by the patented claims and are not patentably distinct from the patented claims. Instant claim 64 corresponds to patented claim 1. Instant claim 65 corresponds to patented claim 2. Instant claim 66 corresponds to patented claim 3. Instant claim 67 corresponds to patented claim 4. Instant claim 68 corresponds to patented claims 5 and 6. Instant claim 70 corresponds to patented claim 7.

23. Claims 64, 66-68 and 71 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over at least claims 13-15, 21, 28, 39 and 42 of U.S. Patent No. 6,673,025. Although the conflicting claims are not identical, they are not patentably distinct from each other because the patented claims recite all of the

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features of the broader claims of the instant application. Therefore, the instant claims are "anticipated" by the patented claims and are not patentably distinct from the patented claims. Instant claim 64 corresponds to patented claims 13, 28, 39 and 42. Instant claims 66-68 correspond to patented claims 14 and 15. Instant claim 71 corresponds to patented claims 21 and 42.

24. Claim 64 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 27 and 62 of copending Application No. 10/631,275. Although the conflicting claims are not identical, they are not patentably distinct from each other because the copending claims recite all of the features of the broader claim of the instant application. Therefore, the instant claim is "anticipated" by the copending claims and is not patentably distinct from the copending claims. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

25. Applicant's arguments with respect to the previous prior art rejection have been fully considered and are persuasive. The prior art rejection of claims 64-70 set forth in the previous Office Action has been withdrawn.

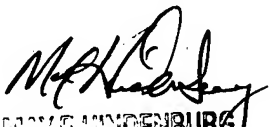
Conclusion

26. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Apanius whose telephone number is (571) 272-5537. The examiner can normally be reached on Mon-Fri 8am-4:30pm.

27. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

28. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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